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Project No.: 713

July 9, 2001

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

Subject: June 12, 2001 Pre-application meeting between US NRC and Exelon Generation regarding the Pebble Bed Modular Reactor (PBMR)

Dear Sir/Madam,

Attachment 1 of this letter captures the Exelon discussion that accompanied the PBMR licensing approach portions of the Exelon meeting with the NRC staff on June 12, 2001. Attachment 2 is a revision of the "Top Level Regulatory Criteria for the Pebble Bed Modular Reactor in the United States," document presented at the June 12, 2001 meeting that provides further explanations and clarifications discussed during the meeting.

Sincerely,

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Attachment 1

Project Number: 713

PBMR Pre-Application Meeting

"June 12, 2001 Meeting Summary
Regarding the PBMR Licensing Approach and
Comparison to
NRC Risk Informed Policies"

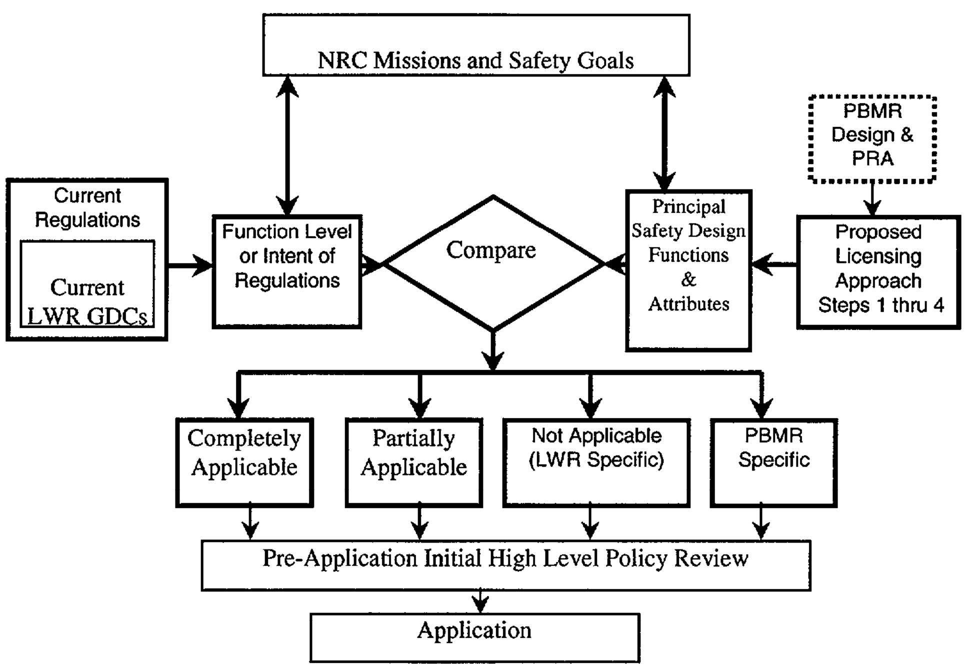
PBMR Licensing Approach:

During the June 12, 2001 PBMR pre-application meeting further clarification regarding the PBMR licensing approach was described by Exelon and is provided below.

The proposed PBMR licensing approach will first apply the steps below in order to assess and define the PBMR design relative to its designed safety principals.

1. Determine the design independent and site independent US top-level quantitative criteria that define the NRC mission and safety goals
2. Determine the design-specific licensing bases events (LBEs) by means of the plant specific PRA
3. Determine the PBMR's applicable principal design safety criteria (i.e., General Design Criteria) by examining the functions and features that prevent the criteria in step 1 from being exceeded (step 2 and step 3 are iterative steps)
4. Classify the systems, structures, and components (SSCs) that provide the safety related functions determined above and ensure the level of regulatory treatment assigned to these SSCs is commensurate with its safety significance.

The information obtained by these four steps will support the licensing bases of the PBMR application, and will be, in part, the criteria used to identify the applicable regulations or will support an exemption from requirements. The figure below was presented at the June 12, 2001 meeting and the bolded areas constitute the PBMR licensing approach methodologies to be review by the NRC staff during the pre-application period.



The purpose of the approach is to provide a scrutable process that will enable both Exelon and the NRC the ability to 'navigate' within the existing regulations while either preparing the application or during its review. Specifically it will provide systematic structured methodologies for selecting the regulatory criteria, the licensing basis events, and the classification of systems, structures and components. Having a risk-informed method provides design criteria, which can be impartially compared to the current regulations where much of the language and purpose has been influenced and written specifically for legacy light water reactor designs. The method allows for the comparison of the design specific technical safety functions to that of the regulation's underlying purpose. PRA methods have been applied successfully in several regulatory activities and have been a valuable complement to deterministic engineering approaches (e.g., back-fit rule, safety goals, Technical Specifications Improvements, severe reactor accidents policy, and reactor siting). In addition, having a risk-informed component provides a means to better understand and measure uncertainty, provides a means to measure the contribution of defense-in-depth and assure it is appropriately allocated, and identify specific design safety issues which may not be addressed in the current regulations. However, the proposed licensing approach may not be applicable to all regulations, especially those with a non-technical bases.

The licensing approach described above can also provide early interaction with the NRC staff regarding the characteristics of the PBMR in relation to the current regulations. Exelon has proposed to utilize the US Department of Energy sponsored Modular High-Temperature Gas-Cooled Reactor (MHTGR) design as a surrogate, since the PBMR detailed design and specific PRA may not be fully developed during the pre-application period. Exelon believes the MHTGR safety design principles are sufficiently similar to those of the PBMR, which will provide proof of the methods, and early regulatory insights into the PBMR design. The results of this pre-application regulatory comparison will provide sufficient detail in order to identify technical or regulatory issues or policies that may need to be resolved prior to submittal of the first PBMR license application.

Comparison of the PBMR Licensing Approach to the NRC Risk Informed Policies:

Also at the June 12, 2001 meeting, Exelon presented a comparison of the proposed approach for licensing the Pebble Bed Modular Reactor (PBMR) with the NRC's policy statements in regard to advanced reactors and the principles of risk informed regulation that are being applied for current generation Light Water Reactors. These principles are reflected in a set of regulatory guides and standard review plans that include Regulatory Guide 1.174 "An Approach for Using Probabilistic Risk assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing basis," and in the efforts to risk inform the General Design Criteria of Part 50 of the Code of Federal Regulations.
The PBMR approach is responsive to the NRC's Policy Statement on Regulation of Advanced Nuclear Power Plants, namely to foster early dialogue and agreement on the approach to be used to license advanced reactors in a manner that enhances the stability and predictability of the process. The policy statement sets forth NRC's

expectations for a reactor's characteristics in order to be regarded as an advance reactor. The policy statement acknowledges that the NRC regards an early gas cooled reactor concepts as qualifying for the advanced reactor designation. There are additional enhancements and innovations in the PBMR design such as passive safety systems, fewer operator actions, and minimum number of components that provide additional reasons to support the PBMR designation as an advanced reactor concept.

A fundamental aspect of the current NRC risk informed activity is the need to address the NRC policy on safety goals and the Quantitative Health Objectives (QHO). The safety goals and QHO are themselves independent of reactor type and, hence, should be expected to apply equally well to all reactors licensed by the NRC. How these goals and objectives are applied, however, needs to take into account the inherent characteristics of individual designs. An insight from PRAs developed for LWRs can be characterized as the following: A necessary and sufficient condition for any LWR accident to produce significant radiological consequences at or beyond the site boundary is to produce a severe core damage accident involving extended uncovery of the active fuel, oxidation of the fuel element cladding, and melting of a significant fraction of the core in a manner that either fails the containment or is accompanied by an independent failure or bypass of the containment. This insight is used to focus PRA evaluations and other evaluations to address the safety goals on the surrogate LWR risk metrics of Core Damage Frequency, (CDF), Large Early Release Frequency (LERF), conditional containment failure probabilities, and other risk metrics such as the various risk importance measures that are derived from these.

While risk metrics such as CDF and LERF may be rather straightforwardly applied to various advanced light water reactor concepts and other types of advanced reactors, they do not apply to the PBMR nor to any of its graphite moderated gas-cooled reactor predecessors. The inherent characteristics of the PBMR preclude core melting. The reactor core and heat removal systems have been designed to retain their physical and structural integrity, and to preclude failure of a significant number of fuel particle coatings over a wide range of accident conditions that correspond to similar conditions in an LWR that would produce core melting. These inherent PBMR characteristics also eliminate fuel coolant interactions, reactivity induced pressure spikes, and core-coolant-containment interactions that are important aspects of LWR accident progression phenomena. The concept of a loss of coolant accident (LOCA) also has no analogue to the PBMR because even though one can postulate depressurization accidents due to failures in the primary pressure boundary, it is not possible to "pull a vacuum" on the primary system and, hence, a total loss of coolant is not credible. Postulating such a condition, is irrelevant to the capability of protecting the fuel elements in the PBMR because the core is designed to be cooled by conduction and radiation to the reactor building without any active heat removal systems or without any forced or natural circulation of helium. Due to these characteristics, the consequences of accident sequences which can be postulated by identifying functional initiating event classes, and various combinations of failures of active systems as is done in a PRA are small. Importantly, there is no single pinchpoint in accident progression, analogous to an LWR core melt event, which leads to a step increase in potential consequences. Hence, one key challenge to developing a suitable risk informed process for the PBMR is the need to develop a different set of risk metrics to replace CDF, and LERF.

The risk metrics that were developed in the MHTGR pre-licensing effort and adapted in the proposed PBMR licensing approach are a set of PBMR specific accident families, and estimates of their frequencies, consequences, and uncertainties presented on a frequency vs. consequence plot. This plot is adapted from similar plots used by the father of PRA, Reginald Farmer, and his colleagues who used PRA to develop criteria for siting gas cooled reactors in the U.K.

In the PBMR, there is no discrete event or plant state such as "core damage" or "large early release" that produces large source terms from the fuel, from the primary pressure boundary, or from the confinement. The potential consequences of PBMR accidents span a continuum over a range of accidents that involve the release of very small sources of radioactivity over long periods of time. The timing and quantity of radioactive material releases in a PBMR accident vary over a limited range and involves participation by several small components of the total radionuclide inventory of the PBMR.

The approach that has been taken to address application of the safety goals and QHOs in the PBMR licensing approach is the same that was used in the MHTGR pre-licensing activity and that is to plot the frequencies and consequences of the major release categories from the PRA with explicit display of the uncertainties in a Frequency-Consequence plot provided by Exelon. This approach was adopted in view of the lack of a counterpart for the LWR risk metrics of CDF and LERF, and is a reasonable approach to deal with a the PRA spectrum of accidents for the PBMR.

The proposed PBMR licensing approach directly addresses the fundamental aspects of the NRC safety goal policy that are reactor independent and adopts a set of risk metrics that are appropriate for the PBMR, account for its unique characteristics, and are analogous to those used in previous risk informed approaches to licensing and siting gas-cooled graphite moderated reactors. The LWR risk metrics of core damage frequency, large early release frequency, and conditional containment failure probability do not apply and are not relevant to discussing the safety characteristics of gas-cooled graphite moderated reactors such as the PBMR.

In summary, while there are significant differences in the accident metrics for LWRs and PBMRs, the US NRC's risk-informed concepts are applicable. As a result of the significant differences in plant design and safety concepts there will be differences in the implementation of the concepts. However, at the philosophical level, consistency is readily achieved.

The NRC's policy statement on probabilistic risk assessment encourages greater use of PRA to improve safety decision making and regulatory efficiency. The NRC has undertaken a number of activities to risk-inform regulations and regulatory processes in order to enhance safety and reduce unnecessary burden.

A NRC risk-informed principle is to ensure that current regulations are not inadvertently undermined through the application of risk-informed concepts. Thus, unless an exemption or rule change is explicitly requested, the current regulations will be applied. The proposed PBMR licensing approach is intended to be applied within the current regulations and any necessary exemptions that may be required to reflect the inherent characteristics to the reactor will be explicitly identified and justified. Thus, the approach is consistent with this principle of risk-informed regulation.

The proposed PBMR licensing approach relies on elements of both the rationalist and the structuralist models described by members of the Advisory Committee on Reactor Safety (ACRS). The existing regulations will be applied (structuralist), except where exemptions are requested, and the risk-informed approach will identify the design basis events, and safety significant components and functions (rationalist).

In relation to the advanced reactor policy statement the design of the PBMR incorporates many risk-informed defense-in-depth concepts. The PBMR design addresses the following list of considerations for defense in depth identified in Reg. Guide 1.174:

- A balance between accident prevention and mitigation,
- No over-reliance on programmatic activities to compensate for weaknesses in plant design,
- System redundancy, independence, and diversity are employed,
- Potential common cause failures are minimize through the use of passive, and diverse active systems to support key safety functions,
- Barriers to fission product release are independent, and
- The potential for human errors is minimized.

Safety margin, in general, connotes the relative conservatism employed in the design or process to assure confidence in the desired result in light of uncertainties in plant behavior during accident conditions. The proposed PBMR approach utilizes a comprehensive risk assessment which includes quantitative consideration of uncertainties to demonstrate that quantitative objectives are met. This allows the examination of contributors to uncertainty and a quantitative assessment of the safety margin. In addition, the uncertainties are accounted for in the identification of licensing basis events and safety significant structures, systems and components. Hence both the design and the safety analysis approach apply the principle of safety margins to assure that safety requirements are met.

The PBMR design incorporates important features to monitor the performance of the primary barrier via monitoring of the circulating fuel activity and the on-line refueling process is capable of detecting poor performance of fuel before the fuel is circulated back into the reactor. In addition, it is anticipated that existing regulatory programs related to performance measurement would be utilized where appropriate depending on the SSC safety functions and their participation in the Licensing Basis Events.

Conclusion:
The proposed PBMR licensing approach was reviewed against advanced reactor design considerations and current risk-informed initiatives. Based on this review, the following conclusions are drawn:

- The PBMR design and licensing approach are compatible with the characteristic of advanced reactors identified in the Advanced Reactor Licensing Policy Statement,
- The approach is compatible with US NRC Safety Goal Policy Statement,
- The approach is compatible with US NRC's principles of risk-informed regulation, and
- The PBMR approach to defense-in-depth and application of safety margins places more reliance on inherent and passive verses active and engineered safety features

Differences in the implementation approach for the risk-informed principles are necessitated by the inherent safety and design features of the PBMR. These features preclude direct application of risk metrics such as core damage frequency, and large early release frequency. However, the PBMR will use risk metrics that are appropriate for its unique characteristics and fundamental differences with LWRs. These risk metrics are the frequencies and dose consequences of a set of Licensing Basis Events that are derived from the PBMR PRA. Therefore, the proposed PBMR licensing approach is compatible with current industry initiatives for risk-informing regulations.

Attachment 2

Project Number: 713

PBMR Pre-Application Meeting

"Top Level Regulatory Criteria
For the Pebble Bed Modular Reactor
In the United States,"

Working draft B

WORKING DRAFT B

TOP LEVEL REGULATORY CRITERIA

FOR THE

PEBBLE BED MODULAR REACTOR

IN THE UNITED STATES

JULY 2001

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1.0 INTRODUCTION

In support of the development and licensing of Modular High Temperature Gas Cooled Reactors (MHTGR), DOE-HTGR-85002 (Reference 1) presented a listing of Top Level Regulatory Criteria (TLRC) to be utilized as standards for judging nuclear power plant licensability related to the retention of radionuclides. These criteria directly specify acceptable numerical limits on radionuclide releases for the protection of public health and safety and the environment. The purpose of this document is to update the previously developed TLRC in support of planned efforts directed toward the licensing of the Pebble Bed Modular Reactor (PBMR).

The purpose of the TLRC is to establish a fundamental and quantitative basis that is both consistent and unambiguous for judging the current acceptability of potential radionuclide releases such that protection of the public health and safety and the environment is adequately maintained. The quantitative regulatory criteria are established to ensure an acceptable level of health and safety as measured by the risks of radiological consequences to individuals and the environment.

The scope of this document is directed toward the following objectives:

- Identification of Top Level Regulatory Criteria
- Identification of Risk-Informed Event Frequency Ranges (applicable to each criterion)
- Assessment of the applicability of the Top Level Regulatory Criteria to the PBMR

Section 2 addresses the bases for the selection of the TLRC. The identification and discussion of current regulatory criteria is presented in Section 3. An assessment of the application of the criteria to the PBMR is discussed in Section 4.

2.0 BASES FOR SELECTION OF TOP LEVEL REGULATORY CRITERIA

The following are the bases for the selection of the TLRC:

1. The TLRC should be a necessary and sufficient set of direct statements of acceptable health and safety as measured by the risks of radiological consequences to individuals and the environment[1].

2. The TLRC should be independent of reactor type and site.

3. The TLRC should use well defined and quantifiable risk metrics.

Basis 1 ensures that the criteria are fundamental to the protection of the public health and safety and the environment.

Basis 2 requires that the criteria be stated in terms that are generic and applicable to all reactor types and sites.

Basis 3 ensures that the achievement of the criteria can be measured or calculated and that the results of these calculations can be used to make unambiguous conclusions that the criteria have been met.

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[1] The term risk as used here implies the definition of a reasonably complete set of event sequences or scenarios, estimates of their frequencies and consequences, and thorough understanding and quantification of uncertainties in these frequency and consequence estimates. Regulatory criteria may be framed in terms of limits on the aggregate risk levels, by limiting the frequencies of event sequences grouped by similar consequences, by limiting the consequences of events in different frequency ranges, or some combination of these approaches. In no case are consequence criteria set independent of frequency and vice versa.

3.0 TOP LEVEL REGULATORY CRITERIA

3.1 Risk Criteria

Based upon the criteria selection bases and a review of current Federal Regulations and other pertinent documents, the following regulatory sources have been identified as containing top-level criteria:

- **Reactor Safety Goal Policy Statement –** As documented in Federal Register, Vol. 51, No. 149, pp. 28044-28049, August 4, 1986 (Reference 3).

- **10CFR20, Standards For Protection Against Radiation, Subpart D -- Radiation Dose Limits for Individual Members of the Public.** These criteria limit the dose consequences of relatively high frequency events and releases that occur as part of normal plant operations.

- **10CFR50, Appendix I, Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents.** These contain cost benefit criteria for normal releases.

- **40CFR190, Environmental Radiation Protection Standards For Nuclear Power Operations.** This regulation specifies both numerical dose criteria intended to protect the health and safety of the public and numerical radionuclide release criteria intended to protect the environment from the consequences of all normal uranium fuel cycle operations.

- **10CFR100, Reactor Site Criteria, Subpart B, Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997.** These criteria impose limits on the radiological consequences associated with low frequency design basis accidents and hypothetical scenarios selected to qualify the location of the site and the site boundary in relation to nearby population zones.

- **10CFR50.34 (a) (1) Content of Applications; Technical Information: Radiological Dose Consequences.**

- **EPA-400-R-92-001, October 1991, U.S. EPA, Manual of Protective Action Guides and Protective Actions for Nuclear Incidents** (Reference 5). These criteria set conditions for initiating offsite emergency protective actions in the event of a threat of significant radiological exposure that would exceed 10CFR20 and Appendix I limits.

The above consequence limits are risk criteria, since the event sequences against which they are applied have understood frequency ranges.

3.1.1 Reactor Safety Goal Policy Statement

The policy statement on reactor safety goals was initiated because of recommendations of the President's Commission on the Accident at Three Mile Island. The content of the policy statement was discussed in many forums before the Commission issued Safety Goals for the Operation of Nuclear Power Plants Policy Statement in 1986, (Reference 3). The Safety Goal Policy Statement expressed the Commission's policy regarding the acceptable level of radiological risk from nuclear power plant operation as follows:

Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.

Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

The following quantitative objectives are used in determining achievement of the above safety goals:

The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.

The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

Although changes have been made to the policy statement based on NRC staff requirements and recommendations memoranda (via SECY-89-102, 97-208, 98-101, 99-191, 00-0077) that have been issued since 1986, no major change in the quantitative objectives noted above and discussed in NUREG-0880, Revision 1 (Reference 4) have been made relative to those presented in Reference 1.

The Reactor Safety Goals do not address environmental considerations, worker protection, nonreactor activities, or special nuclear materials safeguards matters.

As presented in Reference 1, NUREG-0880 provides quantitative data for the determination of incremental risk. This report cites data showing that the individual mortality risk of prompt fatality in the United States is about 5×10^{-4} per year for all accidental causes of death. Applying the prompt mortality risk safety goal for increased incremental risk of no more than 0.1% results in an increase in the individual's annual risk of accidental death by an increment of no more than 5×10^{-7} per year. This is applicable to the average risk for those individuals who reside at a location within 1 mile of the plant site boundary.

NUREG-0880 also notes that, on average, roughly 19 persons per 10,000 population die annually in the United States as a result of cancer, although the geographic and demographic variation is large. Taking the average rate to be 2×10^{-3} per year and applying the delayed mortality risk safety goal of 0.1% would limit the increase in an individual's annual risk of cancer death to an increment of no more than 2×10^{-6} per year. This is applicable to the average risk for those individuals who reside at a location within 10 miles of the plant.

3.1.2 10CFR20

This regulation specifies permissible exposure rates, dose levels and activity concentration in restricted and unrestricted areas. The numerical values given in 10CFR20 have changed (circa 1994) to incorporate updated Federal Radiation Protection Guidance from those given in Reference (1) but continue to be consistent with all the identified bases and are considered TLRC. Major changes included a reduction in limits and the replacement of dose to critical organs with effective dose and the use of committed dose.

3.1.3 10CFR50 Appendix I

This regulatory requirement identifies numerical guidelines for implementing the objective of as low as reasonably achievable (ALARA). The stated dose values presented are based upon light water reactor operating experience and design features in order to be consistent with the objective of being ALARA. Reference (1) proposed that the dose values stated in 10CFR50 Appendix I represent suitable power plant allocations of the overall fuel cycle limits stated by the Environmental Protection Agency in 40CFR190 and in this sense are representative of TLRC.

It should be noted that the cost benefit guideline for judging the necessity for additional radwaste system improvements is not included as a top level regulatory criterion since this guidance is not consistent with the criteria selection basis in Section 2. It is not a direct statement of acceptable risk to the public health and safety or the environment.

3.1.4 40CFR190

As indicated in Reference (1), this regulation specifies both numerical dose criteria intended to protect the health and safety of the public and numerical radionuclide release criteria intended to protect the environment from the consequences of all normal uranium fuel cycle operations. Both limits are consistent with all of the selection bases and are included as TLRC. The specified criteria are unchanged from Reference (1).

As previously specified in Reference (1), the numerical criteria of 40CFR190 and 10CFR50, Appendix I are complementary and the PBMR would be assessed against both. Appendix I provides limits on the dose due to effluents from an individual reactor, including the allocations from shared facilities. In contrast, 40CFR190 sets a limit on exposure from all sources both effluent and direct from the plant fuel cycle. On a site specific basis, one or the other may prove to be more limiting, depending on the existence of any other contributing plants or uranium fuel facilities in the vicinity and the expected types and levels of effluents. Accordingly both Appendix I and 40CFR190 are included as TLRC and the maximum allowable dose to any member of the public shall be the lower of the limits established by their application.

3.1.5 10CFR100

This regulation provides the guidance for determining site suitability for accident radioactive releases and is consistent with all the Section 2 identified bases and therefore qualifies as TLRC. The dose guidance previously specified in Reference (1) has been changed for new power reactor applicants to reflect the Total Effective Dose Equivalent (TEDE) values specified in 10CFR50.34(a)(1).

However, as stated in Reference (1), the analysis assumptions used in implementing these dose guidelines needs to be oriented to the characteristics of the specific reactor type and design. In particular the source term guidance given in TID 14844 (Reference 6) or 10CFR50.67 Accident Source Term as defined in NUREG 1465 (Reference 7) are applicable for light water reactors and are not appropriate for the PBMR. A methodology (Reference 8) for establishing applicable licensing basis events, similar to that developed in Reference 9, needs to be used to determine the appropriate implementation of these dose guidelines and the other TLRC for the PBMR.

3.1.6 10CFR50.34 (a) (1)

This technical content of applications section of the regulation specifies the dose consequence criteria following design basis accidents as:

(1) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE).
(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE.

These numerical values differ from those previously specified in Reference (1) and have been updated to reflect current Federal Radiation Protection guidance similar to the changes made to 10CFR20.

3.1.7 EPA-400-R-92-001

This EPA manual (Reference 5) provides updated guidance for emergency planning and Protective Action Guides (PAGs), replacing those previously given in EPA-520/1-75-001, for exposure to airborne radioactive materials due to a nuclear incident. The PAGs for responses during the early and intermediate phases following an incident are now expressed in terms of the projected sum of the effective dose equivalent from external radiation and the committed effective dose equivalent incurred from inhalation of radioactive materials from exposure and intake. Supplementary guides are also specified in terms of committed dose equivalent to the thyroid and dose equivalent to the skin. This more complete guidance updates and replaces previous values, expressed in terms of whole body dose equivalent from external gamma exposure and thyroid dose equivalent from inhalation of radioactive iodine. However, Reference 5 incorporates directly the PAGs for contaminated foodstuffs previously published by the FDA in 1982 (Reference 12). As before the rationale for the selection of these dose guides is not reactor design specific.

The NRC implementation requirements in 10CFR50 Section 50.47 and Appendix E for emergency planning are unchanged. Therein it is noted that generally a plume exposure pathway Emergency Planning Zone (EPZ) of 10 miles in radius and an ingestion pathway EPZ of 50 miles in radius provide an adequate planning basis. The technical basis for the selection of these EPZ distances is given in NUREG-0396 (Reference 10) wherein it is found for the majority of light water reactors (LWRs) that for all but the most improbable events, the PAGs would not be expected to be exceeded beyond these distances.

It should be noted that 10CFR50, Appendix E continues to state that "the size of the EPZs also may be determined on a case by case basis for gas cooled nuclear reactors and for reactors with an authorized power level less than 250 MW thermal". Therefore, alternative implementation guidance, similar to that proposed by DOE for the MHTGR per Reference 11, using the PAGs as the numerical criteria for determining appropriate EPZ distances needs to be assessed for the PBMR.

As noted earlier, even though the above criteria appear to limit consequences and are not framed in the context of risk they are still regarded as risk criteria because there are implied scenarios and frequency ranges that are used with the consequence criteria.

3.2 Frequency Regions

The development of Frequency Regions is performed in the manner described in Reference (1) and consists of a spectrum of releases covering a frequency range from normal operation to very low probability off-normal events. As presented in Reference (1) the spectrum of potential accidental radioactive releases from a plant are divided in the following three regions in a scenario frequency vs. consequence chart.

- Anticipated Operational Occurrences (AOO)
- Design Basis Events (DBE)
- Emergency Planning Basis Events (EPBE)

An examination of the entire frequency range and the identification of one or more of the TLRC as being applicable for each Region provide assurance that the selected criteria are adequately established. A summary of the TLRC and their applicable frequency ranges are provided in Table 3-1.

3.2.1 Anticipated Operational Occurrences Region

Anticipated Operational Occurrences are those conditions of normal operation which are expected to occur one or more times during the life of the plant. Using a licensing basis design lifetime of 40 years yields a lower boundary for the AOO region of 2.5×10^{-2} per plant year. For this Region, 10CFR50, Appendix I has been chosen as the applicable criteria as it specifies the numerical guidance to assure that releases of radioactive material to unrestricted areas during normal reactor operations, including AOOs, are maintained As Low As Reasonably Achievable (ALARA).

3.2.2 Design Basis Event Region

The Design Basis Event Region encompasses releases that are not expected to occur during the lifetime of one nuclear power plant. The frequency range covers events that are expected to occur during the lifetime of a population (several hundred) of nuclear power plants; and therefore a lower limit of 10^{-4} per plant year is chosen. This frequency is believed to be consistent with the existing LWR design basis region even though LWR design basis accidents were not determined from a quantitative assessment of frequency. Estimates of LWR core damage accidents, which exceed the design basis, have been in the range of $1x10^{-5}$ to greater than $1x10^{-4}$. For this region, 10CFR100 and 10CFR50.34 (a)(1) provide the quantitative dose guidance for accidental releases for siting a nuclear power plant to ensure that the surrounding population is adequately protected.

3.2.3 Emergency Planning Basis Event Region

The Emergency Planning Basis Event Region considers improbable events that are not expected to occur during the lifetime of several hundred nuclear power plants. This is to assure that adequate emergency planning is developed to protect the public from undesirable exposure to radiation for improbable events. The frequency cutoff implicit in the acute fatality risk goal in NUREG-0880 is taken as the lower frequency boundary of the EPBE Region. NUREG-0880 notes that the individual mortality risk of prompt fatality in the U. S. is about 5×10^{-4} per year for all accidental causes of death. The prompt mortality risk design objective limits the increase in an individual's annual risk of accidental death to 0.1% of 5×10^{-4}, or an incremental increase of no more than 5×10^{-7} per year. If the frequency of a scenario or set of scenarios is at or below this value, it can be assured that the individual risk contributions from these scenarios would still be within the safety goal independent of the magnitude of consequences. Therefore this value is used as the lower frequency bound for the EPBE Region.

TABLE 3-1

TOP LEVEL REGULATORY CRITERIA

Policy Statement of Reactor Safety Goals

Purpose: To specify acceptable incremental risk of prompt and delayed fatality to an individual and the population due to local siting of a power plant.

Frequency Range: Normal Operation to 5×10^{-7} per plant year

1. Individual Prompt Mortality Risks:

   The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result form reactor accidents should not exceed 0.1% of the sum of prompt fatality risks resulting from other accidents to which members of the U. S. population are generally exposed.

   Based on the quantitative regulatory guidance documents (References 2 and 4), the incremental risk to the average individual within 1 mile of a nuclear power plant site boundary shall be no more than 5×10^{-7} per plant year.

2. Individual Delayed Mortality Risk:

   The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes.

   Based on the quantitative regulatory guidance documents (References 2 and 4), the incremental risk to the average individual within 10 miles of a nuclear power plant site boundary shall be no more than 2×10^{-6} per plant year.

10CFR20

Purpose: To specify acceptable occupational and public exposures and offsite releases in effluents.

Frequency Range: Normal Operation to 2.5×10^{-2} per plant year

1. Section 20.1201 - Occupational dose limits for adults.

   An annual limit, which is the more limiting of:

Table 3-1 (Cont'd)

(i) the total effective dose equivalent being equal to 5 rem (0.05 Sv); or
(ii) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

The annual limits to the lens of the eye, to the skin, and to the extremities, which are: (i) a lens dose equivalent of 15 rem (0.15 Sv), and (ii) a shallow-dose equivalent of 50 rem (0.50 Sv) to the skin or to any extremity.

Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix B to Part 20 and may be used to determine the individual's dose (see §20.2106) and to demonstrate compliance with the occupational dose limits.

The dose that an individual may be allowed to receive in the current year shall be reduced by the amount of occupational dose received while employed by any other person (see §20.2104(e)).

2. Section 20.1301 –Dose limits for individual members of the public:

   Total effective dose equivalent (TEDE) < 100 mrem per year.

   Dose in unrestricted area from external sources < 2 mrem in any one hour.

3. Section 20.1302 – Compliance with dose limits for individual members of the public

   Demonstrate by measurement or calculation that the TEDE to the individual likely to receive the highest dose does not exceed the annual dose limit or demonstrate that:
   (i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to Part 20 and
   (ii) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 2 mrem in an hour and 50 mrem in a year.

10CFR50 Appendix I

Purpose: To specify acceptable offsite exposures during normal operation and anticipated events for an individual reactor.

Frequency Range: Normal operation to 2.5×10^{-2} per reactor year.

Table 3-1 (Cont'd)

Section II: Guides on design objectives for LWRs:

1. Paragraph A:

   Estimated annual dose from liquid effluents: ≤ 3 mrem total body, or ≤ 10 mrem to any organ.

2. Paragraph B:

   Estimated annual dose from gaseous effluents: ≤ 5 mrem total body or ≤ 15 mrem to the skin.

3. Paragraph C:

   Estimated annual dose from all radioactive iodine and radioactive material in particulate form in effluents to the atmosphere: ≤ 15 mrem to any organ.

40CFR190

Purpose: To specify acceptable offsite exposures and releases due to the entire uranium fuel cycle.

Frequency Range Normal operation to 2.5×10^{-2} per reactor year.

1. Section 190.10 (a) – Annual dose equivalent to a member of the general public from uranium fuel cycle operations (as defined in 190.02).

   Whole body dose: ≤ 25 mrem
   Thyroid dose: ≤ 75 mrem
   Any other organ dose: ≤ 25 mrem

2. Section 190.10 (b) – Total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle, per gigawatt-year of electrical energy produced by the fuel cycle:

   Kr-85 < 50,000 curies
   I-129 < 5 millicuries
   Pu and other α emitting and transuranic nuclides with half-lives:
   > 1 yr < 0.5 millicuries.

Table 3-1 (Cont'd)

<u>10CFR100/10CFR50.34 (a) (1)</u>

Purpose: To specify acceptable offsite exposures resulting from unanticipated off-normal events.

Frequency Range: 2.5×10^{-2} to 1×10^{-4} per plant year

1. An individual located at any point on the boundary of the exclusion area for <u>any</u> 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem TEDE.
2. An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE.

<u>Dose Protective Action Guides (PAGs) of EPA 400-R-92-001</u>

Purpose: To specify offsite exposures at the plume exposure or ingestion pathway EPZ for initiating public protection due to airborne and food pathway radioactive materials resulting from unanticipated off-normal events.

Frequency Range: 2.5×10^{-2} to 5×10^{-7} per plant year

1. Protective Action Guides for Early Phase of Nuclear Incident (Exposure to Airborne Radioactive Materials):

Protective Action	**PAG Projected Dose**
Evacuation (or Sheltering) for general population if dose	> 1 to 5 rem[a]
Administration of stable iodine:	> 25 rem[b].

Dose Limits for Workers Performing Emergency Services (rem[c]):

All Activities	5
Protecting Valuable Property	10
Lifesaving or protection of large populations	25
(on a voluntary basis to persons fully aware of risks)	>25

[a] The sum of the effective dose equivalent resulting from exposure to external sources and the committed effective dose equivalent incurred form all significant pathways during the early phase. Committed dose equivalents to the thyroid and to the skin may be 5 and 50 times larger, respectively.
[b] Committed dose equivalent to the thyroid from radioiodine
[c] Sum of external effective dose equivalent and committed effective dose equivalent to non-pregnant adults from exposure and intake during an emergency situation. Workers performing

Table 3-1 (Cont'd)

services during emergencies should limit dose to the lens of the eye to 3 times the listed value and doses to any other organ (including skin and body extremities) to 10 times the listed value. These limits apply to all doses from an incident, except those received in unrestricted areas as members of the public during the intermediate phase of the incident.

2. Protective Action Guides for Exposure to Deposited Radioactivity During the Intermediate Phase of a Nuclear Incident

Protective Action	**PAG Projected Dose**[d]
Relocate the general population (beta dose to the skin may be up to 50 times higher).	≥ 2 rem
Apply simple dose reduction techniques	< 2 rem

[d] The projected sum of effective dose equivalent from external gamma radiation and committed effective dose equivalent from inhalation of resuspended materials, from exposure or intake during the first year. Projected dose refers to the dose that would be received in the absence of shielding from structures or the application of dose reduction techniques.

3. Protective Action Guides for Exposure from Materials via the Food Pathway

Protective Action	**PAG Projected Dose**
Preventive:	0.5 rem[e] 1.5 rem[f]
(Preventive action is to reduce the radioactive contamination of human food or animal feed)	
Emergency:	5 rem[e] 15 rem[f]
(Emergency action is to isolate food containing radioactivity to prevent its introduction into commerce and the level at which the responsible officials should determine whether condemnation or another disposition is appropriate.)	

[e] Dose to the whole body, bone marrow or any other organ.
[f] Dose to the thyroid

4.0 TOP LEVEL REGULATORY CRITERIA APPLIED TO PBMR

As was done in the Reference (1), the regulatory criteria developed and presented in Section 3 are basically applicable to all nuclear power reactor types inclusive of the PBMR. The consequence criteria are based upon current regulation and regulatory guidance. The frequency criteria represent a reasonable quantification derived from current regulatory sources. Recognizing that some interpretation may be appropriate and that more stringent criteria may be imposed by the plant user and designer, specific applications of the criteria have been adopted for a PMBR.

4.1 Module Versus Plant Or Site

In the evaluation of the PBMR, the consequence criteria given in Table 3-1 (including 10CFR50 Appendix I) are numerically taken to be independent of a reactor plant, i.e., the criteria apply to a plant regardless of the number of reactors or modules. However, the criteria are for the licensing application of a new plant, which may or may not be on a site with existing, previously licensed reactors/plants. The existence of multiple modules would increase the frequency of single module related scenarios and create the potential for scenarios involving multiple modules concurrently. By contrast, in the case of LWRs safety goals and other relevant criteria have been applied to each reactor unit independently.

4.2 Distance Criteria

The dose guidelines of 10CFR50.34 (a) (1) apply to an individual located at any point on the boundary of the exclusion area for <u>any</u> 2 hour period following the onset of the postulated fission product release, and to an individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release, during the entire period of its passage.

The safety goals for prompt and delayed mortality are applied at one and ten miles, respectively. However, for the PBMR, all offsite dose criteria and safety goals are to be met for the maximum exposed individual at the boundary of the exclusion area.

4.3 PBMR Application of Risk Criteria

The application of the consequence and risk criteria for the PBMR is performed in a manner similar to that performed for the MHTGR in Reference (1). However as presented in Table 3-1 the changes that have been made to the specification of dose criteria for 10CFR20, 10CFR100, and PAG projected doses in terms of committed and effective dose equivalents (i.e. TEDE) makes the consistent application of the regulatory dose consequences values over the range of frequencies not as easily illustrated as in Reference (1). However with the recognition of the changes in regulatory bases, the application of the TLRC across the spectrum of potential accident frequency ranges is presented in Figure 4-1.

4.3.1 10CFR50 Appendix I

The dose criteria are expressed in terms of the expected annual dose at the site boundary along the plume centerline. Hence, for an event expected to occur twice per year the total dose from two events is compared to the Appendix I annual limit. This is used to derive an equivalent allowable dose for each event. For frequent events occurring more than once a year, this results in the sloped risk line shown in Figure 4-1. For less frequent events within the plant lifetime, no single event may exceed the allowable dose as indicated by the vertical dose line in the figure. Appendix I is the most limiting requirement of those identified for normal operation and anticipated operational occurrences

4.3.2 10CFR100 / 50.34.(a) (1)

In the design basis region, acknowledgement that relatively more frequently occurring events should meet more stringent criteria leads to the sloping dose criteria line. At the lower end (i.e. 10^{-4} per plant year), the criteria are 100% of the limit dose. The criteria linearly decrease to the upper end where 10% of the limit is used. This is consistent with the NRC's qualitative criterion, as reflected in the Standard Review Plan guidance, that the dose limitations from more frequent accidents be a fraction of the dose guidelines. The dose criteria are expressed in TEDE at the site exclusion area boundary (EAB). The 10CFR100 / 50.34.(a) (1) criteria are more limiting than the Reactor Safety Goals.

4.3.3 Prompt Mortality Safety Goal

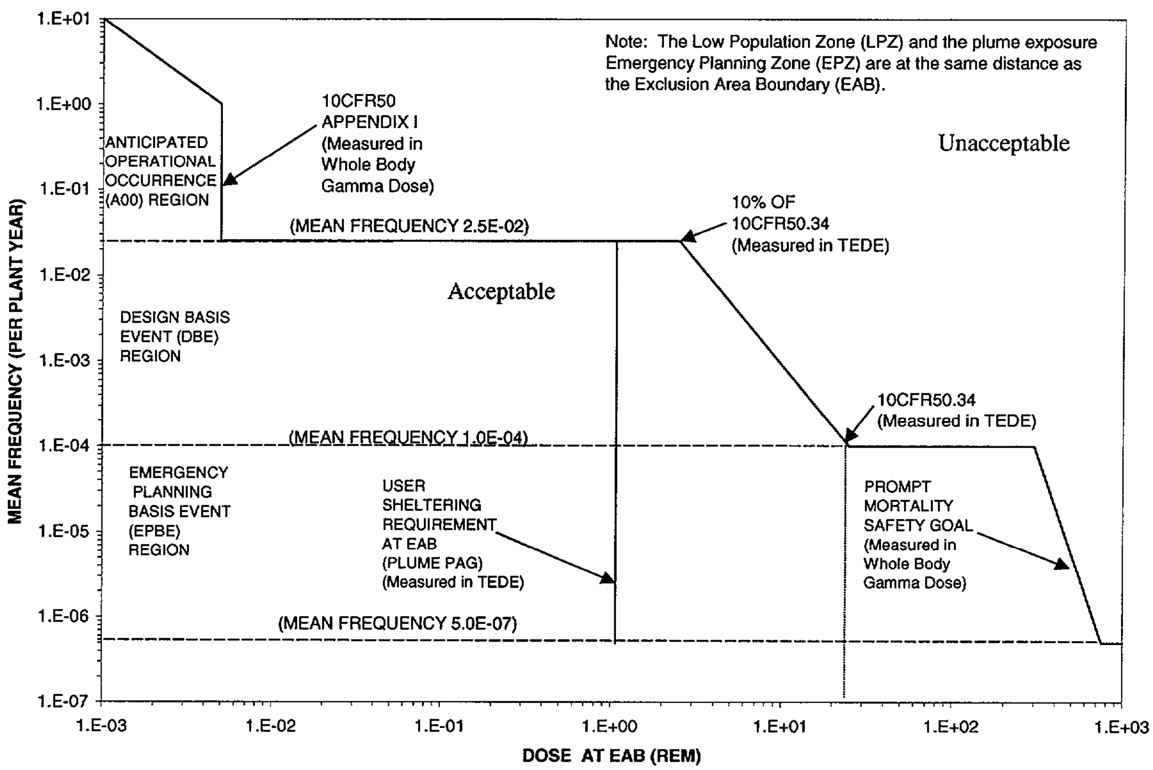
The incremental mortality cancer risk allowed by the safety goal is 5×10^{-7} fatalities per year. The illustration of the prompt mortality risk curve displayed in Figure 4-1 is approximated and presented in terms of whole body dose in rem. The prompt mortality risk is more limiting than the latent fatality risk. The use of the safety goals to draw the criteria line in this region is very conservative when applied to the dose at the site boundary along the plume centerline as a person at this point would be located at the point of maximum risk over the area within 1-mile of the site boundary in which the average individual risk must meet the safety goal. When the individual risk at this point meets the safety goal, the average individual risk within 1-mile of the site boundary would be much less than 5×10^{-7} per year value.

4.3.4 Dose Protective Action Guides

Protective Action Guidelines (PAG) from EPA-400-R-92-001 are shown as a dose limit as expressed in TEDE at the emergency planning zone (EPZ). The

PAG apply to the design and emergency planning basis regions. Depending on the size of the EPZ, the PAG can be the most limiting criteria. The PBMR will be designed with the option to preclude the need for offsite sheltering, that is, the EPZ would be at the EAB (for sites without existing nuclear power plants with larger EPZ).

FIGURE 4-1
APPLICATION OF TOP LEVEL REGULATORY CRITERIA FOR THE PBMR



5.0 REFERENCES

1. "Top-Level Regulatory Criteria for the Standard MHTGR," Department of Energy Report, DOE-HTGR-85002, Revision 3, September 1989.

2. Staff Requirements Memorandum to W. D. Travers, Executive Director of Operations, Re: SECY-00-0077 – Modifications to the Reactor Safety Goal Policy Statement, dated June 27, 2000.

3. "Safety Goals for the Operation of Nuclear Power Plants," Policy Statement, Federal Register, Vol. 51, No. 149, pp.28044-28049, August 4, 1986.

4. "Safety Goals for Nuclear Power Plant Operation, U. S. Nuclear Regulatory Commission Report, NUREG-0880, Rev. 1, (For Comment), May 1983.

5. "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents", U.S. Environmental Protection Agency, EPA-400-R-92-001, October 1991.

6. "Calculation of Distance Factors for Power and Test Reactors", Technical Information Document 14844, Division of Reactor Licensing and Regulations, AEC, dated March 23, 1962.

7. "Accident Source Terms for Light Water Nuclear Power Plants", U. S. Nuclear Regulatory Commission Report, NUREG-1465, February 1995.

8. "Licensing Basis Events for the Modular HTGR, "Department of Energy Report, DOE-HTGR-86-034, Rev. 1, February 1987.

9. Reilly, H. J., et al., "Preliminary Evaluation of HTGR Severe Accident Source Terms", EG&G Idaho, Inc. Report EGG-REP-6565, April 1984.

10. "Planning Basis for the Development of State and Local Governmental Radiological Emergency Plans in Support of Light Water Nuclear Power Plans", U. S. Nuclear Regulatory Commission and U. S. Environmental Protection Report, NUREG-0396:EPA 520/1-78-015, December 1978.

11. "Emergency Planning Bases for the Standard MHTGR", Department of Energy Report DOE-HTGR-87-001, Rev. 1, August 1987.

12. "Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies", Federal Register, Vol. 47, No. 205, pg 47073, October 22, 1982.